Amendments to the Drawings:

The attached drawing sheet includes changes to FIG. 1. No other figures are shown on the sheet.

Attachment: 1 Replacement Sheet

1 Annotated Sheet Showing Changes

Remarks/Arguments

1. Applicant thanks Examiner for the careful review of the present application, as evidenced by the Office Action of September 27, 2007. In that Office Action, Examiner rejected all pending claims 5-11.

2. **Amendments to the Specification:** Language further describing the two subsystems of the vitality-preserving fluid circulation system, the vitality-preserving fluid circulation system and the dialysate circulation system, was added to paragraph [0012]. The first sentence of this amendment is taken verbatim from paragraph [0008] of the Specification as originally filed. The reference designations **51** and **52** were added to the sentence, to illustrate the connections of the dialysate and the perfusate circulation systems to the organ chamber. Language was also added to clarify that the dialysate circulation system is connected to the organ perfusion chamber and the perfusate circulation system to the hepatic blood vessels, as shown in FIG. 1 as originally filed. This amendment introduces no new subject matter, as it is well known in the field that the perfusate circulation system is connected to the organ, in order to circulate perfusate through the organ, and it is clear from the description in paragraphs [0012] and [0013] that the dialysate circulation system is connected to the organ perfusion chamber, which serves as a reservoir for the dialysate that is used in the dialysate circulation system. Applicant requests approval and entry of the amended paragraph.

3. **Amendments to the Claim:** Claim 5 was amended to more clearly recite the components of the vitality-preserving fluid circulation system, that the storage fluid, a dialysate, flows from the organ perfusion chamber into the dialysate circulation system, and the storage of the organ within the protective cover. Language supporting this amendment is found in paragraph [0009] of the Substitute Specification as originally

filed and in FIG. 1, which shows the inlet and outlet connections of the dialysate circulation system to the organ perfusion chamber. Claim 5 was further amended to recite a wall of the organ perfusion chamber that has connectors for connecting to said organ and a protective cover that encloses the organ in a space defined by the protective cover and the wall of the organ perfusion chamber, so as to provide a complete barrier between the organ and the storage fluid. FIG. 1 as originally filed clearly shows the protective cover up against a portion of the wall that has the connectors for connecting the perfusate circulation system to the organ, such that a complete barrier to the storage fluid is provided. These amendments introduce no new subject matter and Applicant requests approval and entry of the amended claim.

4. **Amendments to the Drawings:** Reference designations 51 and 52 were added to FIG. 1, to more clearly illustrate the connections of the perfusate circulation system to the organ and the dialysate circulation system to the reservoir. The person of skill in the art knows that the liver has three major blood vessels, the Arteria Hepatica, the Vena Portea, and the Vena Cava and that the perfusate circulation system is connected to these vessels, such that prepared, dialyzed blood is circulated into the Arteria Hepatica and the Vena Portea. Thus, it is clear to a person of skill in the art, that the perfusate circulation system is connected to the organ itself. It is also known that the two other smaller vessels in the liver that are not included in the perfusate circulation system connections are used to drain off bile and liver secretions. Paragraphs [0008] , [0012], and [0013] clearly describe that the storage fluid in the organ perfusion chamber is a dialysate and that it flows into the dialysate circulation system. A person of skill in the art, reading the description and looking at FIG. 1 would immediately understand that the perfusate circulation system is connected to the organ and the dialysate circulation system to the organ storage chamber.

5. Applicant submits that the amendments to the drawing introduce no new subject matter and requests approval and entry of the amended FIG. 1.

6. **Nonstatutory Double Patenting Rejection:** Applicant requests that this provisional double-patenting rejection be held in abeyance, until the co-pending application is examined.

7. **Rejections under 35 U.S.C. § 112:** Examiner rejected claims 5-10 as being indefinite for failing to particularly point out and distinctly claim the subject matter being claimed. Particularly, Examiner asserts that it is unclear whether the vitality-preserving fluid and the storage fluid are two distinct fluids or a mixture of the two fluids and that it is unclear as to how the dialysate or the dialysate circulation system are integrated into the vitality-preserving fluid circuit.

8. FIG. 1 has been amended to clarify the relationships of the perfusate circulation system to the organ and the dialysate circulation system to the organ perfusion chamber. The basic method of maintaining the vitality of the organ stored in the organ perfusion chamber is a well known method referred to as normothermic extracorporeal liver perfusion (NELP). An Information Disclosure Statement for this application was filed on May 19, 2006, which lists a medical journal article by Michael R. Schoen: LIVER TRANSPLANTATION AFTER ORGAN PRESERVATION WITH NORMOTHERMIC EXTRACORPOREAL PERFUSION, Annals of Surgery, Vol. 233, No. 1, pages 114 – 123, 2001. This prior art reference discloses a normothermic extracorporeal liver perfusion (NELP) circuit. See Figure 1 on page 116. The NELP circuit is a vitality-preserving fluid circuit that includes a dialysate circulation system and a perfusate circulation system. The dialysate is used to remove metabolic waste products from the perfusate that has circulated through the organ. The perfusate is

cleaned in the dialysate circulation system and pumped back into the perfusate circulation system, which in turns re-circulates the perfusate through the organ, in this case, a liver, in the organ storage chamber.

9. A Supplemental IDS is being filed concurrently with this paper, which lists the dissertation TRANSPLANTATION VON LEBERN NICHT-HERZSCHLAGENDER SPENDER IM SCHWEINELEBER-TRANSPLANTATIONSMODELL, submitted by Michael R. Schoen in 1999 to the Medical Faculty Charité at the Humboldt University in Berlin. The title page, table of contents, and pages 16 – 18 and 40 are enclosed. Pages 16 – 18 describe a vitality-preserving fluid circuit that comprises a perfusate circuit and a dialysate circuit. This reference was made available to the public in 1999. In his dissertation, Dr. Schoen describes normothermic extracorporeal liver perfusion (NELP) as a method of preserving livers for transplantation and to reverse warm ischemic injury. The apparatus used for NELP is a perfusion circulation system that includes a first circulation system that circulates perfusate, a second system that circulates dialysate, and a third circulation system that circulates water heated to about 37 degrees C in an external heat exchanger through the organ perfusion chamber. A portion of the perfusate that is collected after it has passed through the organ is circulated through the dialysate circuit, where it is dialyzed and then passed on to the oxygenator. See particularly Fig. 10 on page 41, which is a schematic illustration of the perfusion system used by Schoen in his experiments, and which is identical to the schematic illustration shown in the article published in the Annals of Surgery in 2001, cited above. A translation of the relevant passages is also included.

10. The two prior art references discussed above show that a vitality-preserving fluid circuit comprising a dialysate circulation system and a perfusate circulation system is

well known in the art. It is well known that the perfusate circulation system is connected to blood vessels of the organ to be maintained, so that the perfusate flows into, through, and out of the organ. The person of skill in the art knows that the perfusate is pumped into the Arteria Hepatica and the Vena Portea and out through the Vena Cava. The person of skill also knows that the perfusate is prepared, dialyzed or cleaned blood or blood product. The metabolic waste products in the perfusate exiting the organ are cleaned with a dialyzer, which is connected to a dialysate circulation system. It is also known, that the dialysate can take up only so much of the waste product and that it is necessary to connect a relative large storage container of dialysate into the dialysate circulation system, in order to renew the dialysate. For example, Michael Schoen discloses in the 1999 Dissertation the use of a ten-liter dialysis reservoir to store dialysate that is used to replenish or renew spent dialysate. Schoen, Dissertation, page 18.

11. The vitality-preserving fluid circulation system is a necessary component of the organ storage system of the present application, but such a system comprising the perfusate circulation system and the dialysate circulation system is known. The patentable features of this organ storage system are 1) storage of an organ in a floating state in an organ perfusion chamber, and 2) use of the organ perfusion chamber as a reservoir for dialysate. These features are adequately described in the Specification and in FIG. 1. Thus, Applicant submits that the claims of the present application are not indefinite, and that a person of ordinary skill in the art of NELP would understand that the vitality-preserving fluid circulation system may have two sub-circuits, one a perfusate circulation system and one a dialysate circulation system. The person of ordinary skill in the art would understand that the perfusate is collected after passing through the organ and that all of it or a portion of it is pumped through the dialysate

circuit to clean the perfusate, add electrolytes to it, and that the perfusate is then re-circulated via the perfusate circulation system into the organ.

12. At the bottom of page 3, top of page 4 of the Office Action, Examiner asserts that claim 5 is indefinite, because it is unclear what products of the dialysate and the perfusate circulation system are included in the vitality-preserving fluid. The comments and arguments presented above provide clarification of the vitality-preserving fluid circulation system and the prior art adequately discloses the integration of the perfusate circulation system and dialysate circulation system into the overarching vitality-preserving fluid circuit. Applicant submits that claim 5 is not indefinite and requests that Examiner withdraw the 35 U.S.C. § 112 rejections.

13. **Rejection under 35 U.S.C. § 102(b):** Examiner rejected claims 5 and 6 over Brasile (U.S. Patent Application Publication 2002/012988 A1), asserting that claim 5 or 6 did not have a limitation that the organ be enclosed instead of being cradled. Claim 5 has been amended to recite a limitation that the protective cover encloses the organ within a space defined by the protective cover and a portion of the wall of the chamber, and that the cover provides a complete barrier between the organ and the storage fluid. Brasile discloses a method of supporting an organ on a pad or in a sling 36. The organ is not maintained in a floating state. Rather, liquid is drained from the organ and drips down into a reservoir 38 beneath the organ support. Brasile does not disclose enclosing the organ in a protective cover and maintaining the organ in a floating state within a chamber that is filled with dialysate, and the simultaneous use of the chamber as a reservoir for dialysate.

14. Examiner also asserted that Brasile discloses floating an organ on a liquid reservoir, saying that FIG. 2 shows a design in which inherently includes suspending

the organ in a flexible sack so that it floats on the liquid reservoir beneath. Actually, it is undesirable to have the effluent, i.e., the perfusate that exits the organ, to come into contact with the organ. Paragraph [0021] clearly states that the venous outflow of the preservation solution is directed away from the organ, so as to inhibit contact of the preservation solution with the outer surface of the organ. See also paragraph [0074] in Brasile, in which it is explained that the effluent is collected by gravity flow and that a length of tubing 43 is connected to the venal outlet, presumably to prevent the effluent from coming into contact with the organ. FIG. 1 does not show the support member floating on liquid, but rather, shows a container 38 for the effluent reservoir beneath the support member 36. The support member 36 is much larger than the reservoir 38 and cannot possible be floating on liquid in that reservoir. FIG. 4 is a more complete illustration of the system, showing the effluent reservoir 38 as a separate container beneath the organ support 36, with the level of liquid in the container well below that of the underside of the support member 36.

15. Claims 6 and 11 depend from claim 5 and contain the subject matter of claim 5.

16. Applicant submits that Brasile does not anticipate currently amended claim 5 and therefore requests that this rejection be withdrawn.

17. **Rejections under 35 U.S.C. § 103(a):** Examiner rejected claims 1 – 11 as being obvious in view of Brasile (pages 7 – 8 of the Office Action) and further in view of Bacchi et al. (U.S. Patent 5,285,657; 1994). Brasile or Bacchi, either alone or in combination, do not teach, suggest, or motivate one skilled in the art to use the organ perfusion chamber as a reservoir for dialysate that is used in the dialysate circulation system and to enclose the organ in a protective cover, which provides a barrier between the dialysate that is stored in the chamber and the organ. Thus, these prior art references

do not render claim 5 obvious. All other claims of the present application depend from claim 5 and, thus, contain all the limitations of claim 5.

18. Applicant submits that claims 5 – 11 contain allowable subject matter and requests that Examiner withdraw all rejections and allow all claims currently presented.

19. Examiner is respectfully invited to call or email the Undersigned, should there be any issues that can be quickly clarified with this type of communication.

20. This paper is being filed within three months of the issue date of the Office Action. No additional late fees or other fees are due. Should, however, other fees be deemed necessary, the Undersigned herewith authorizes permission to deduct such fees as necessary from the Deposit Account No. 501 517.

21. Applicant herewith informs Examiner that the underlying German patent application issued as EP patent DE 103 40 488 B4 on May 10, 2007, a copy of which is enclosed herewith.

Respectfully submitted,

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December 20, 2007
IDS & Translation of passages
Annotated Drawing Sheet
Replacement Drawing Sheet
EP Patent DE 103 40 488 B4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/570835	Confirm. No.: 8773
Filing Date:	3/3/2006	
Inventor:	Joachim ARZT et al.	
Title:	EXTRACORPOREAL ORGAN CONSERVATION	
Art Unit:	1651	
Examiner:	Underdahl, Thane E.	
Attorney Docket No.:	06022	

To: Commissioner for Patents

Transmitted via EFS

TRANSLATOR'S STATEMENT

English-language translation of excerpts from dissertation submitted by Dr. Med. Michael R. Schoen to the Humboldt University, Berlin, 1999

I, the Undersigned, hereby state that I am fluent in the German language, and that I certify that the enclosed translation of the excerpts is complete and accurate.

Respectfully submitted,

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Date: December 20, 2007

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Translation of Excerpts from Dissertation of Michael R. Schoen, Berlin 1999, that was listed in the IDS Filed May 19, 2006

Page 16

2.1.2 PERFUSATE CIRCULATION SYSTEM

The perfusion apparatus comprised:

- two roller pumps (Stoeckert Company, Munich), such as are used in heart-lung-machines
- a membrane oxygenator (Cobe CML Disposable Membrane Oxygenator, Cobe, Munich)
- a temperature-controllable reservoir
- a catch basin, as well as
- a silicon hose system (Silicon Tubing, Aromado Medizin Technik, Duesseldorf), which was used to connect the various components with each other and which enables a recirculating perfusion.

Temperature control was accomplished by means of a heat exchanger (Stoecker, Munich) and pressure control by means of a pressure transducer upstream of the liver artery. This perfusate circulation system corresponded substantially to one that was used in a previous project. [56]

Following an ischemic period of 90 minutes, the liver was placed in the catch basin, which was filled with perfusion solution that had been heated to 37 degree C. The Vena portae and the Arteria hepatica were now connected to the perfusate circulation system and the perfusion started. The Arteria hepatica was degassed via the Arteria gastroduodenalis, which was still open, and then

ligated. The Vena portae was degassed by filling the cannula before connection to the hose system.

The Vena portae was passively perfused with the perfusate in the filler reservoir of the membrane oxygenator by gravity flow. The pressure thus obtained corresponded to a water column of 10 – 20 cm, depending on the resistance of the liver. The Arteria hepatica was perfused with controlled pressure from the liquid reservoir, by means of a roller pump. The mean pressure was between 60 – 80 mmHg. With reference to the weight of the liver, a total flow of approximately 1- 2 ml/g min was achieved. The portalvenal flow was about 2/3 and the arterial flow about 1/3 of the total flow volume.

Drainage from the liver was done via the Venae hepaticae and the Vena cava inferior into the catch basin. The second roller pump pupmped perfusate from the catch basin through the oxygenator into the reservoir. Carbogen (95% oxygen, 5% carbon dioxide) was circulated through the oxygenator. The actual temperature of the perfusate was measured in the hose system before the perfusate entered the liver, in order to regulate the temperature of the perfusate to 37+/-0.25 degrees C.

The flow diagram of the circulation system is shown in Figure 1.

Page 17:

Perfusate

The perfusate used was based on a solution that is similar in its composition to plasma. This solution, designated HPF 3, comprises a crystalline portion and a colloid solution, the gelatine polypeptide (Haemaccel 35, Behring Werke,

Marburg).[62,63] Three liters of HPF 3 were added to one liter of whole blood, which resulted in a hemoglobuline value of approximately 5 g/dl, with a hematocrit of approximately 18%. Table 1 provides the composition of the HPF3. Twenty mg of Tobramycin (Lilly, Giessen) were added before the perfusion was started, for bacteriostasis reasons.

Page 18:

Dialysate Circulation System

The perfusion apparatus was expanded in Group 2 to include a dialysate circulation system. The dialysate circulation system was connected as a bypass (Fig. 1). One-fifth of the perfusate flow was taken downstream of the catch basin and pumped into the dialysate circulation system and back into the perfusate circulation system upstream of the oxygenator.

The dialysate circulation system comprised two roller pumps (Stoeckert, Munich), a dialyzer (Gambro ALWALL GFS 12 Fiber Dialyzer, Gambro, Hechingen), and an open 10 liter supply container, which held the dialysate.

A roller pump pumped the perfusate through the capillary system of the dialyzer and back into the perfusate circulation system. The second roller pump pumped the dialysate in the reverse flow direction. Pressures were measured on the perfusate and dialysate side in each case upstream of the dialyzer. The pressure differential across the membrane was selected such that no liquid flowed from one compartment into the other compartment, in order to avoid any volume displacements between the perfusate and the dialysate. The volume was regulated via flow adjustment on the perfusate side and the dialysate side by maintaining pressure equilibrium on both sides of the capillaries.

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Dialysate Circulation System and Oxygenation

A dialyzer was integrated into a circulation system, that is separate from and independent of the prevailing pressures and flows in the liver perfusate circulation system. This fiber dialyzer NT 1375 (Spiraflo Biomedica, Saluggia, Italy) has an effective surface area of 1.35 m^2. 300 ml dialysate was pumped by one roller pump per minute over a heat exchanger (720 Helios, Dideco, Mirandola, Italy), which heated the dialysate to 37 degrees C and perfusate was pumped by a second roller pump through the dialyzer, depending on the total amount of blood.

Fig. 10: Schematic Diagram of the perfusate circulation system.

Page 41:

Figure 10. Schematic Diagram of a Perfusion Circuit

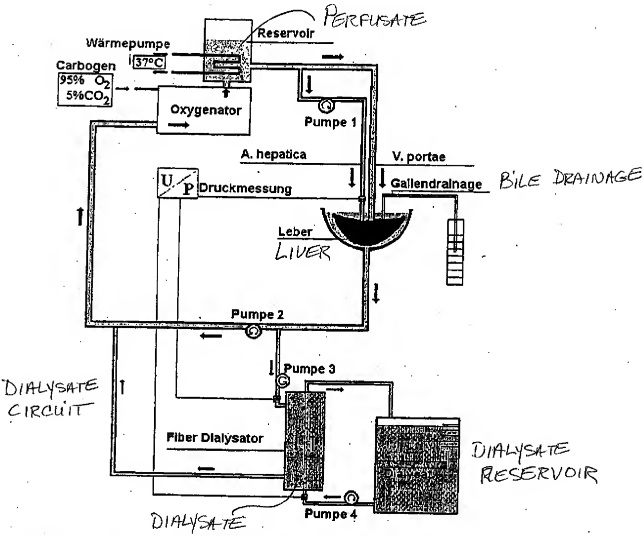

Abbildung 1: Schema des Perfusionssystems

FIGURE 1

Perfusat

Das verwendete Perfusat basierte auf einer in seiner Zusammensetzung dem Plasma ähnlichen Lösung. Bezeichnet wird diese Lösung als HPF 3. Sie besteht aus einem kristallinen Anteil und einem kolloidalen Lösungsmittel, dem Gelatine-Polypeptid (Hämaccel 35, Behring Werke, Marburg) [62,63]. 3 Liter HPF 3 wurden zu 1 Liter Vollblut gegeben. Daraus resultierte ein Hämoglobinwert von etwa 5 g/dl mit einem Hämatokrit von ca. 18%. Tabelle 1 gibt die Zusammensetzung von HPF 3 wieder. Vor Beginn der Perfusion wurden zur Bakteriostase einmalig 20 mg Tobramycin (Lilly, Gießen) zugegeben.

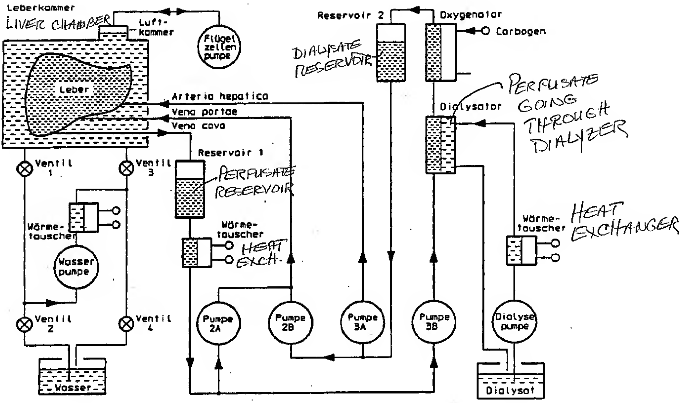

Abbildung 10: Schema des Perfusionssystems

FIGURE 10

Perfusat, Dialysat und Perfusion

Für alle Perfusionen wurde Perfusat auf der Basis von Vollblut benutzt. Das Vollblut stammte aus dem Penrose Schlachthof in Eberswalde, Brandenburg, und wurde frühmorgens am Versuchstag geholt. Nach Betäubung durch Elektroschock und Ankoppeln des Schweins an die Transportschiene wurde die Halsregion abgespritzt und sterilisiert. Die Halsgefäße wurden durchtrennt und das Blut über einen sterilen Trichter in einem sterilen 5l-Kanister aufgefangen. Zur Antikoagulation wurden pro Liter 500 IE Heparin zugegeben. Anschließend erfolgte der Transport ins Forschungshaus der Charité, Campus Virchow-Klinikum.

2,5l Blut wurden durch Zugabe von 1,5 l Jonosteril auf eine Hämoglobinkonzentration von 10-11 g/dl eingestellt. Das Gesamtvolumen des Perfusats betrug 4l.

Die Ausgangswerte der untersuchten Parameter sind als Mittelwerte ± Standardfehler angegeben und wurden aus dem für die Perfusion der Gruppen 3 und 6 verwendeten Vollblut ermittelt.

APPLICATION No. 10/570,835 ANNOTATED SHEET

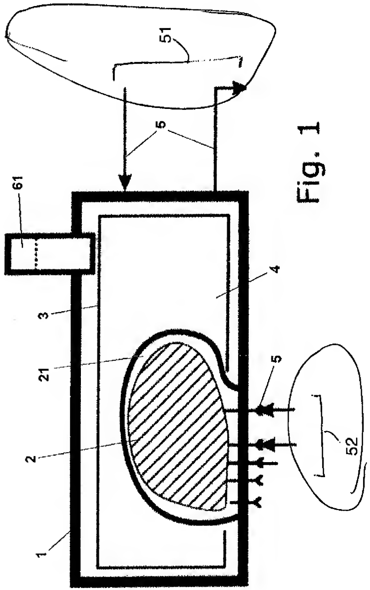

Fig. 1

APPLICATION NO. 10/570,835 REPLACEMENT SHEET

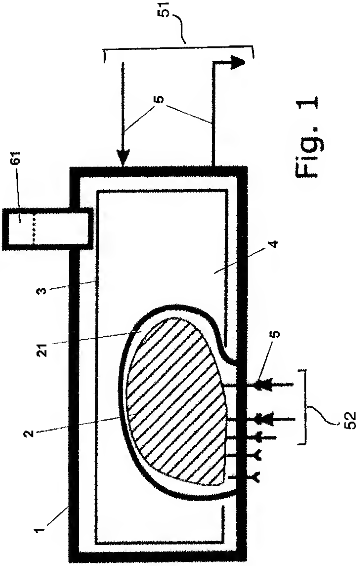

Fig. 1

(19) Bundesrepublik Deutschland
Deutsches Patent- und Markenamt

(10) **DE 103 40 488 B4 2007.05.10**

(12) **Patentschrift**

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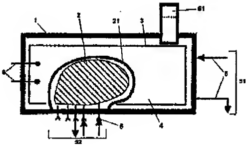
(56) Für die Beurteilung der Patentfähigkeit in Betracht gezogene Druckschriften:
Neuhaus, Peter: Extrakorporale Leberperfusion-Entwicklung und Erprobung eines neuen Modells. Habilitationsschrift, 1982, Medizinische Hochschule Hannover;

(54) Bezeichnung: **Extrakorporale Organaufbewahrung**

(57) Hauptanspruch: Anordnung zur extrakorporalen Organaufbewahrung mindestens bestehend aus einer Organperfusionskammer (1) mit einer regelbaren Temperatureinrichtung (3) und einem darin eingelagerten Organ (2), wobei das Organ (2) von einer impermeablen Schutzhülle (21) ummantelt und im weiteren vollständig von einer Lagerflüssigkeit (4) umgeben ist, dadurch gekennzeichnet, daß die Lagerflüssigkeit (4) das Dialysat ist, welches Bestandteil eines vitalerhaltenden Kreislaufes (5), der aus einem Dialysatkreislauf (51) und einem Perfusatkreislauf (52) besteht, ist.



Beschreibung

[0001] Die Erfindung betrifft eine Anordnung zur extrakorporalen Organaufbewahrung, die in bekannter Weise dazu dient, die Vitalfunktionen von Organen künstlich aufrecht zu erhalten oder zu regenerieren. Im folgenden soll der Begriff Organe auch Extremitäten und Gewebelappen und dergleichen umfassen; Organ wird dementsprechend als Oberbegriff verwendet.

[0002] Ein wichtiges Einsatzgebiet ist insbesondere der Organtransport oder im weiteren biochemische oder pharmakologische Untersuchung an isolierten Organen.

[0003] Einrichtungen für die Perfusion isolierter Organe sind bekannt.

Stand der Technik

[0004] Bereits Anfang der 80er Jahre entwickelte Neuhaus, P. eine geschlossene und druckoszillierende Leberperfusion (Extrakorporale Leberperfusion: Entwicklung und Erprobung eines neuen Modells – Habilitationsschrift. 1982; Medizinische Hochschule Hannover). Hierbei befindet sich die Leber in einer flüssigkeitsgefüllten, geschlossenen Perfusionskammer, auf die von außen zyklische Druckschwankungen, welche Atemexkursionen nachahmen, angelegt werden. Die Gefäßlumina folgen den künstlichen intraabdominellen Druckschwankungen. Das Perfusionsergebnis konnte durch diese Perfusionstechnik, insbesondere in der Läppchenperipherie, deutlich verbessert werden. Des weiteren wird die großflächige Ausbildung von unterperfundierten Arealen vermieden, die bedingt durch die Größe und des damit verbundenen Gewichts von Schweinelebern bei der bis dahin herkömmlichen Lagerung auf der Unterseite auftraten. Die Perfusionskammer ist mit einem seitlichen Reservoir ausgestattet. Selbstredend war diese neue Versuchsapparatur dadurch und auch sonst gerätetechnisch aufwendig und praktisch nicht mobil einsetzbar.

[0005] Schön, M. R. verwendet in einer Perfusionseinrichtung eine solche flüssigkeitsgefüllte geschlossene Organperfusionskammer mit zyklischen Druckschwankungen zur normothermen extrakorporalen Leberperfusion (Transplantation von Lebern nicht-herzschlagender Spender im Schweineleber-Transplantationsmodell – Habilitationsschrift 1999. Humboldt Universität zu Berlin). Die vorgeschlagene Organperfusionskammer wird von Wasser durchströmt, das mit einem externen Wärmetauscher auf etwa 37 °C erwärmt wird. Dieser Kreislauf ist zusätzlich zum Perfusionskreislauf und zum Dialysatkreislauf erforderlich.

Aufgabenstellung

[0006] Der Erfindung liegt die Aufgabe zugrunde, einen möglichst einfachen Aufbau einer Anordnung zur extrakorporalen Organaufbewahrung zu schaffen. Insbesondere bei der Transplantationschirurgie ist der Transport – und die Aufrechterhaltung der Funktionsfähigkeit der Organe – eine wesentliche Aufgabe einer teilweise weltweit operierenden Organ- und Transplantationslogistik.

[0007] Diese Aufgabe wird erfindungsgemäß durch die kennzeichnenden Merkmale des Hauptanspruches gelöst.

[0008] Weitere vorteilhafte Ausführungen ergeben sich aus den nachfolgenden Ansprüchen.

[0009] Die erfindungsgemäße Anordnung zur extrakorporalen Organaufbewahrung besteht mindestens aus einer Organperfusionskammer mit einer regelbaren Temperatureinrichtung.

[0010] In dieser Organperfusionskammer ist ein Organ eingelagert, welches von einer Schutzhülle ummantelt ist. Die Schutzhülle ist vorzugsweise als impermeabler Kunststoffbeutel ausgeführt. Das derart geschützte Organ ist vollständig schwebend in einer Lagerflüssigkeit eingelagert.

[0011] Der Erfindung liegt der Gedanke zugrunde, das ohnehin vorhandene Dialysat als Lagerflüssigkeit zu nutzen. Das Dialysat ist ein wesentlicher Bestandteil zur Aufrechterhaltung der Vitalfunktionen des Organs und infolge dessen auch wesentlicher Bestandteil des vitalerhaltenden Kreislaufes zur Versorgung des extrakorporalen Organs. Erfindungsgemäß wird ein notwendiger Dialysatkreislauf und die dazu notwendigen Aggregate genutzt, die Lagerflüssigkeit als Dialysat in den Dialysatkreislauf einzubinden und die Organperfusionskammer gleichzeitig als Speicher für das Dialysat zu verwenden.

[0012] Die Organperfusionskammer ist flüssigkeits- und druckdicht hermetisch geschlossen. Neben der medizinischen Notwendigkeit ist damit insbesondere eine Transportfähigkeit per Flugzeug und Hubschrauber gewährleistet.

[0013] Die Bewandung der Organperfusionskammer, die Schutzhülle und das Dialysat sind transparent ausgeführt.

[0014] Eine regelbare Temperatureinrichtung schafft für das extrakorporale Organ eine normotherme oder hypotherme Umgebungstemperatur. Die Temperatureinrichtung ist bevorzugt als Heizmatte ausgeführt, die den Boden der Organperfusionskammer auskleidet. Die Strömung des Dialysats sorgt für eine gleichmäßige Temperierung des isolierten Or-

gans. In einer weiteren bevorzugten Ausführungsform ist die Temperatureinrichtung durch Wärme- bzw. Kälteschleifen in die Bewandung der Organperfusionskammer integriert.

[0015] Mehrere Meßsonden nehmen Kenngrößen und Parameter, beispielgebend Füllstand, Druck, Temperatur auf und machen diese Signale für eine Anzeigeeinrichtung oder eine digitalen Prozeßsteuerung verarbeitbar.

Ausführungsbeispiel

[0016] Im folgenden wird ein Ausführungsbeispiel der Erfindung anhand der beigefügten Zeichnung näher erläutert.

[0017] Fig. 1 zeigt eine Schemadarstellung einer Anordnung zur extrakorporalen Organaufbewahrung. Die Anordnung besteht aus einer transparenten Organperfusionskammer **1**. Die Organperfusionskammer ist mit Schnellverschlüssen flüssigkeits- und druckdicht hermetisch abgeschlossen. Als Organ **2** ist in dieser Ausführung eine Leber bei normothermer Temperatur eingelagert. Die Schutzhülle **21** ist ein impermeabler, transparenter Kunststoffbeutel.

[0018] Das ummantelte Organ **2** ist vollständig in einer Lagerflüssigkeit **4** schwebend eingelagert. Die Lagerflüssigkeit **4** ist ein Dialysat und ist ein Bestandteil des vitalerhaltenden Kreislaufes **5**. Eine regelbare Temperatureinrichtung **3** ist als Heizmatte in der Organperfusionskammer **1** integriert. Mehrere Meßsonden **6** liefern Signale für eine Prozeßsteuerung, und eine Füllstandsanzeige **61** verdeutlicht den Füllstand der Lagerflüssigkeit **4**. Senkrecht auf der Organperfusionskammer **1** ist als Mittel zur Füllstandsanzeige **61** beispielgebend ein Steigrohr aufgesetzt. In Fig. 1 ist dieses Steigrohr um 90° in die Blattebene gedreht.

[0019] Die in der Zeichnung verwendeten Bezugszeichen haben folgende Bedeutung:

Bezugszeichenliste

1	Organperfusionskammer
2	Organ
21	impermeable Schutzhülle
3	regelbare Temperatureinrichtung
4	Lagerflüssigkeit/Dialysat
5	Vitalerhaltender Kreislauf
51	Dialysatkreislauf
52	Perfusionskreislauf
6	Meßsonden
61	Füllstandsanzeige

Patentansprüche

1. Anordnung zur extrakorporalen Organaufbewahrung mindestens bestehend aus einer Organperfusionskammer (**1**) mit einer regelbaren Temperatureinrichtung (**3**) und einem darin eingelagerten Organ (**2**), wobei das Organ (**2**) von einer impermeablen Schutzhülle (**21**) ummantelt und im weiteren vollständig von einer Lagerflüssigkeit (**4**) umgeben ist, **dadurch gekennzeichnet**, daß die Lagerflüssigkeit (**4**) das Dialysat ist, welches Bestandteil eines vitalerhaltenden Kreislaufes (**5**), der aus einem Dialysatkreislauf (**51**) und einem Perfusatkreislauf (**52**) besteht, ist.

2. Anordnung nach Anspruch 1 dadurch gekennzeichnet, daß die Organperfusionskammer 1 flüssigkeits- und druckdicht abgeschlossen ist.

3. Anordnung nach Anspruch 1 dadurch gekennzeichnet, daß die Bewandung des Organperfusionskammer (1) und das Dialysat (4) transparent sind.

4. Anordnung nach Anspruch 1 dadurch gekennzeichnet, daß die regelbare Temperatureinrichtung (3) als Heizmatte ausgeführt ist.

5. Anordnung nach Anspruch 1 dadurch gekennzeichnet, daß die regelbare Temperatureinrichtung (3) in der Bewandung der Organperfusionskammer (1) integriert ist.

6. Anordnung nach Anspruch 1 dadurch gekennzeichnet, daß in dem Dialysat (4) Meßsonden (6) eingebracht sind.

Es folgt ein Blatt Zeichnungen

Anhängende Zeichnungen

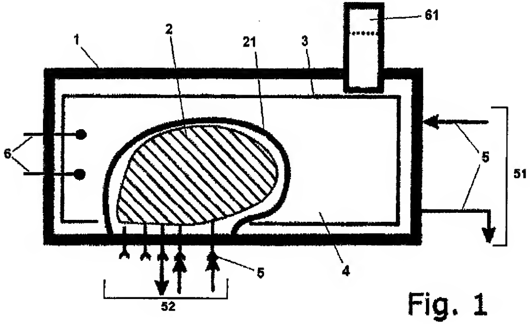


Fig. 1